

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

CONSTANCE GRUSHESKY

Civil Action No.:

Plaintiff,

vs.

3M COMPANY,
a Delaware corporation, and
ARIZANT HEALTHCARE, INC.,
a Delaware corporation,

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, CONSTANCE GRUSHESKY, by and through Plaintiff's undersigned attorneys brings this Complaint against Defendants 3M COMPANY and ARIZANT HEALTHCARE, INC.(hereinafter referred to collectively as "Defendants"),and alleges as follows:

This is an action for damages relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying and/or selling the defective device sold under the trade names of Bair Hugger Forced Air Warming device (hereinafter "Bair Hugger", or "Defective Device").

I. PARTIES

1. At all times relevant to this action, Plaintiff was a resident of Newhall, California.

2. Defendant 3M is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located in Maplewood, Minnesota. 3M is

engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Bair Hugger.

3. Defendant Arizant is a corporation organized and existing under the laws of the State of Delaware, Arizant conducts business throughout the United States, including the State of Minnesota, and is a wholly owned subsidiary of Defendant 3M.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000. Defendants are subject to *in personam* jurisdiction in this court, and venue is proper within this district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendants 3M Company ("3M") and Arizant Healthcare, Inc. ("Arizant") (collectively the "Defendants") conducted substantial business in this district. Defendants did (and do) business within the state of Minnesota and have had substantial, continuous, and systematic contacts with the state of Minnesota, have consented to jurisdiction in the state of Minnesota, and/or committed a tort in whole or in part in the state of Minnesota, and many other states, against thousands of Plaintiffs, including Plaintiff herein, as more fully set forth below. On information and belief, Defendants also marketed, advertised, and sold the defective devices in the District of Minnesota, and many other states, made material omissions and representations in each of these districts, and breached warranties in these districts.

III. SUMMARY OF THE CASE

5. The Defendants, directly or through their agents, apparent agents, servants or

employees designed, manufactured, marketed, advertised, distributed and sold the Bair Hugger.

6. As a result of the defective design of the Bair Hugger, Plaintiff has suffered and may continue to suffer severe and permanent personal injuries.

7. On March 7, 2011, the Bair Hugger was used on Plaintiff during the course of Plaintiff's left hip replacement surgery.

8. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in a gram negative bacterium infection.

9. Due to the infection, Plaintiff was ordered to take antibiotics for eighteen months with an additional surgical procedure to remove the implant and clean the infected area, and Plaintiff continues to suffer substantial damages, including but not limited to taking antibiotics for the duration of her life and impaired mobility, making the simple movement of walking a challenge.

10. Plaintiff now suffers and will continue to suffer from permanent damages as a result of the Bair Hugger-induced infection.

11. The Defendants concealed and continue to conceal their knowledge of the Bair Hugger's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

12. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the Bair Hugger.

13. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the Bair Hugger, which has caused and will continue to cause Plaintiff's various injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

IV. FACTUAL BACKGROUND

14. More than 50,000 Bair Hugger units are currently in use across the country.

15. The Bair Hugger consists of a portable heater/blower connected by a flexible hose to a disposable blanket that is positioned over (or in some cases under) surgical patients. The system warms patients during surgery by blowing hot air on a patient's exposed skin.

16. The hot air produced by Bair Hugger accumulates under the surgical drape covering the patient and escapes from under the surgical drape below the level of the surgical table or at the head end of the surgical table. This escaped air creates air flow currents that flow against the downward air flow of the operating room. As this warmed air rises, it deposits bacteria from the floor of the surgical room into the surgical site.

17. At some point between 2002 and 2009 the Defendants reduced the efficiency of the air filtration of Bair Hugger blowers. This action reduced the safety of such blowers.

18. As a result of these actions by the Defendants, the internal airflow paths of Bair Hugger blowers become contaminated with pathogens.

19. The pathogens contaminating the internal airflow paths of Bair Hugger blowers incubate and proliferate therein.

20. These pathogens are then expelled from the interior of the Bair Hugger blower by the outward airflow, travel through the hose into the disposable blanket and escape into the operating room.

21. The Defendants have been aware of the pathogenic contamination of the airflow paths of Bair Hugger blowers since at least 2009.

22. The Defendants have actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries despite their knowledge to the contrary.

23. In a communication to the Food and Drug Administration ("FDA") in September 2000, Defendants represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time Defendants made it

and it remains false today. To meet HEPA standards, an air filter must be capable of removing 99.97% of all particles 0.3 microns or larger. The filter of the Bair Hugger, which is marketed as HEPA compliant, is only capable of removing less than 65% of all such particles. When the Defendants made these representations, they had actual knowledge of their falsity.

24. In June of 1997, in a letter to the FDA, the Defendants admitted that “air blown intraoperatively across the surgical wound may result in airborne contamination.” The Defendants addressed this flaw in their products by making further misrepresentations to the FDA when they stated that the risk of contamination by air flow is obviated because all “Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent [sic] air from migrating toward the surgical site.” That statement by the Defendants was and is patently false. A number of Bair Hugger blankets marketed as safe for use in surgeries do not utilize a taped edge at all. Instead, those blankets blow contaminated air directly toward the surgical field. Also, the statement that the taped barrier would contain the contaminated air is false because it ignores the fact that the heated air from the Bair Hugger rises against the general downward airflow of the operating theatre. The presence of a tape edge does nothing to prevent the Bair Hugger from facilitating the movement of pathogens from the floor of the operating room to the surgical site. When the Defendants made these representations, they had actual knowledge of their falsity.

25. In their website, www.fawfacts.com/laminar_airflow/ (last visited July 17, 2015), the Defendants make the following misrepresentations:

- a. Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because “[a]ir velocity within the operating room is many times stronger than that of a forced-air warming blanket”;
- b. “The air emerging from the blanket is directed downward by the surgical drape and emerges under the operating room table and is drawn away through the laminar system’s return air inlets;”

- c. “It’s been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket.”

26. The statements in the preceding paragraph are false and intentionally misleading. Through these statements, the Defendants disguise the fact that the issue is not the strength of the airflow in a laminar system but the heat of the air generated by the Bair Hugger. The cold air circulated with the operating room, having a higher density than the air heated by the Bair Hugger, falls to the floor which forces the contaminated air at the floor of the operating room, now warmed by the waste heat from the Bair Hugger, to rise into the sterile field and the surgical site. The heated air rises, and is not “drawn away” as the Defendants falsely claim in their advertisement.

27. In an advertisement that appeared in multiple medical publications as early as 2010, available online at http://www.fawfacts.com/_asset/zn062p/AJIC.pdf (last visited July 17, 2015), the Defendants made the following false and deliberately misleading claims:

“While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems.”

As published scientific research, before and after this statement, has demonstrated, this statement is untrue. The exhaust generated by the Bair Hugger creates convective airflow patterns which disrupt the laminar flow of the operating theater.

28. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, the Defendants’ public relations and communications specialist Greta Deutsch stated “some conductive-warming manufacturers have alleged that forced-air warming increases

bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis.” Again, this statement ignores numerous published studies documenting the adverse effects the Bair Hugger has on laminar airflow.

29. The publication of numerous peer-reviewed studies identifying and documenting the critical safety shortcomings of the Bair Hugger should have prompted the Defendants to redesign or discontinue their product. Instead, those criticisms only caused the Defendants to amplify their efforts to champion the Bair Hugger. These publications include, but are not limited to, the following:

- a. Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010;39:321-8;
- b. Leaper D, et al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009;1(2):e28;
- c. McGovern, P.D., et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br.* 2011;93-B(11):1537-1544;
- d. Legg, A. et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg-Br.* 2012;94-B:254-6;
- e. Belani, K., et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia & Analgesia* 2012 (prepublication on-line) 2013;117(2):406-411;
- f. Dasari, K.B., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012;67:244-249.

30. The effect of these misrepresentations was to mislead healthcare providers about the safety of the Bair Hugger for use in surgical procedures. The Defendants were aware of the falsity of their misrepresentations at the time those misrepresentations were authored.

31. Rather than alter the design of their product or warn physicians of the dangers associated with the Bair Hugger, as numerous studies confirm, the Defendants have chosen to

“double down” on their efforts to promote their defective product.

32. Plaintiffs’ physicians relied upon the above representations and advertisements to Plaintiff’s detriment. Any reasonable and competent physician would not use a Bair Hugger in an orthopedic implant surgery if they were fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public, the medical community, and the FDA, the Defendants actively and knowingly concealed the propensity of these devices to cause infection in orthopedic implant surgeries.

33. As a result of the failure of the Defendants’ Bair Hugger to maintain the sterility of the surgical area and the Defendants’ wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff’s physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of the Defendants’ acts, omissions and misrepresentations.

V. CAUSES OF ACTION

COUNT ONE - NEGLIGENCE

34. Plaintiff restates the allegations set forth above as if fully rewritten herein.

35. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger.

36. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

- a. Failing to properly and thoroughly test the Bair Hugger before releasing the device to market;
- b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of the Bair Hugger;

- c. Failing to conduct sufficient post-market testing and surveillance of the Bair Hugger;
- d. Designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Bair Hugger and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
- e. Failing to exercise due care when advertising and promoting the Bair Hugger; and
- f. Negligently continuing to manufacture, market, advertise, and distribute the Bair Hugger after Defendants knew or should have known of its adverse effects.

37. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered a gram negative bacterium infection, requiring an additional surgical procedure to clean the infected area and remove the hip implant, and the plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting condition and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

38. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate

to punish the Defendants and deter them from similar conduct in the future.

**COUNT TWO - VIOLATION OF MINNESOTA'S CONSUMER PROTECTION
AND DECEPTIVE TRADE PRACTICES LAWS**

39. Plaintiff restates the allegations set forth above as if fully rewritten herein.

40. The Defendants have violated and continue to violate Minnesota Consumer Protection statutes, Minn. Stat. §§ 325F.67; 325F.69 and Minnesota's Deceptive Trade Practices statutes, Minn. Stat. §§ 325D.44.

41. The Defendants are corporations who intentionally sell merchandise, including the Bair Hugger, to consumers, including consumers in Minnesota. The Defendants made false statements in their advertisement of the Bair Hugger, in violation of Minn. Stat. § 325F.67.

42. In advertising the Bair Hugger through various means in Minnesota, including but not limited to television, radio, internet, the products label, pamphlets and letters, the Defendants made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

43. Similarly, the Defendants also acted with, used, or employed fraud, false pretense, false promise, misrepresentation, misleading statements or deceptive practices with the intent that consumers, including Plaintiff, rely on said statements or actions in connection with the sale of the merchandise, in violation of Minn. Stat. § 325F.69.

44. Defendants violated the Minnesota consumer protection laws through, *inter alia*, the following:

- a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;
- b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, qualify, or grade when it differs

materially from that representation;

- c. Representing through statements and advertisement that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect;
- d. Falsely stating, knowingly or with reason to know, that services or repairs are not needed.

45. As a direct and proximate result of the Defendants' actions, omissions, and misrepresentations, Plaintiff suffered a gram negative bacterium infection, requiring an additional surgical procedure to clean the infected area and remove the hip implant, and plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

46. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT THREE - STRICT LIABILITY

47. Plaintiff restates the allegations set forth above as if fully rewritten herein.

48. The Defendants, or entities under their control, manufactured, sold, distributed,

marketed or supplied the Bair Hugger in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

49. Specifically, the Defendants failed to warn of the injuries suffered by Plaintiff as a result of using the Bair Hugger, and they introduced into the stream of commerce a defectively designed or manufactured product.

50. The Defendants designed, manufactured, sold, distributed, supplied, marketed or promoted the Bair Hugger, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

51. Plaintiff and Plaintiff's physicians used the Bair Hugger in a manner normally intended, recommended, promoted and marketed by the Defendants.

52. The Bair Hugger failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

53. The propensity of the Bair Hugger's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger unreasonably dangerous when used in the way it is ordinarily used and is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

A. Strict Liability - Failure to Warn

54. Plaintiff restates the allegations set forth above as if fully rewritten herein.

55. Because the Defendants researched, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the Bair Hugger and in doing so, directly advertised or marketed the product to the

FDA, health care professionals, and consumers, or persons responsible for consumers, they had a duty to warn of the risks associated with the use of the Bair Hugger.

56. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's physician, of the true risks of the Bair Hugger, including that the Bair Hugger would circulate contaminated air in the operating room and that the vented heat from Bair Hugger would mobilize floor air contaminated with pathogens into the surgical site, causing deep joint infections, and requiring further treatment, including surgery or amputation.

57. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physicians, would have used Bair Hugger and no patient, including Plaintiff, would have allowed use of the Bair Hugger.

58. The failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger to Plaintiff or Plaintiff's physician rendered the Bair Hugger unreasonably dangerous.

59. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant. In addition, the plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity of the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalizations, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and

suffering and loss of wages and wage earning capacity.

60. The Defendants' conduct described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

B. Strict Liability - Defective Design and Manufacture

61. Plaintiff restates the allegations set forth above as if fully rewritten here.

62. The design of the Bair Hugger or its component parts, makes the Bair Hugger unreasonably dangerous, taking into consideration the utility of the device and the risk involved in its use.

63. At all times relevant to this action, an economically and technologically feasible safer alternative design existed, which in reasonable medical probability:

- a. would have prevented or significantly reduced the risk of Plaintiff's infection and subsequent injuries (including additional surgical procedures to clean the infected area and/or remove the implant);and
- b. would not have impaired the utility of the device

64. Specifically, the Bair Hugger is defective in its design in that it is not reasonably fit, suitable or safe for its intended purpose or its foreseeable risks exceed the benefits associated with its design.

65. The defective condition of the Bair Hugger rendered it unreasonably dangerous or not reasonably safe and the Bair Hugger was in this defective condition at the time it left the hands of the Defendants. The Bair Hugger was expected to and did reach Plaintiff and Plaintiff's physicians without substantial change in the condition in which it was designed,

manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

66. Defendants knew or should have known of the danger associated with the use of the Bair Hugger, as well as the defective nature of the Bair Hugger, but have continued to design, manufacture, sell, distribute, market, promote, or supply the Bair Hugger so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bair Hugger.

67. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant. In addition, plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss wages and wage earning capacity.

68. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT FOUR - BREACH OF EXPRESS WARRANTY

69. Plaintiff restates the allegations set forth above as if fully rewritten herein.

70. The Defendants expressly represented to Plaintiff and other consumers and the medical community that the Bair Hugger was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

71. The Bair Hugger does not conform to the Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injury.

72. At all relevant times, the Bair Hugger did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

73. Plaintiff, other consumers, and the medical community reasonably relied upon the Defendants' express warranties for the Bair Hugger.

74. At all relevant times, the Bair Hugger was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendants.

75. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

76. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger . Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss wages and wage earning capacity.

77. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT FIVE - BREACH OF IMPLIED WARRANTY

78. Plaintiff restates the allegations set forth above as if fully rewritten herein.

79. The Defendants designed, manufactured, distributed, advertised, promoted and sold the Bair Hugger.

80. At all relevant times, the Defendants knew of the use for which the Bair Hugger was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

81. The Defendants were aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

82. Plaintiff, Plaintiff's physician, and the medical community reasonably relied upon the judgment and sensibility of the Defendants to sell the Bair Hugger only if it was indeed of merchantable quality and safe and fit for its intended use.

83. The Defendants breached their implied warranty to consumers, including Plaintiff; the Bair Hugger was not of merchantable quality or safe and fit for its intended use.

84. Consumers, including Plaintiff, Plaintiff's physician, and the medical community reasonably relied upon the Defendants implied warranty for the Bair Hugger.

85. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

86. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant. In addition, plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

87. The Defendant's conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT SIX - NEGLIGENT MISREPRESENTATION

88. Plaintiff restates the allegations set forth above as if fully rewritten herein.

89. The Defendants made negligent misrepresentations with respect to the Bair Hugger including, but not limited to, the following particulars:

- a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that

Bair Hugger has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and

- b. The Defendants represented the Bair Hugger was safer than other patient warming systems.

90. Defendants did not exercise reasonable care or competence in obtaining or communicating the information to the public regarding the characteristics and qualities of the Bair Hugger.

91. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the representations.

92. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

93. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT SEVEN - FRAUDULENT MISREPRESENTATION

94. Plaintiff restates the allegations set forth above as if fully rewritten herein.

95. The Defendants made fraudulent misrepresentations with respect to the Bair Hugger including, but not limited to, the following particulars:

- a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Bair Hugger has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and
- b. The Defendants represented Bair Hugger was safer than other patient warming systems.

96. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks of Bair Hugger to consumers, including Plaintiff, and the medical community.

97. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

98. The Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Bair Hugger.

99. Plaintiff and Plaintiff's physicians did in fact rely upon the representations. In the absence of the Defendants' representations, the Bair Hugger would not be used in implantation surgeries such as the one at issue in this case.

100. The Defendants' fraudulent representations evidence their callous, reckless, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

101. As a direct and proximate result of the Defendants' actions, omissions and

misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant. In addition, plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

102. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNTH EIGHT - FRAUDULENT CONCEALMENT

103. Plaintiff restates the allegations set forth above as if fully rewritten herein.

104. Defendants fraudulently concealed information with respect to the Bair Hugger including, but not limited to, the following particulars:

- a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Bair Hugger was safe and fraudulently withheld and concealed information about the substantial risk of using Bair Hugger; and
- b. The Defendants represented that Bair Hugger was safe and safer than other alternative systems and fraudulently

concealed information that demonstrated that Bair Hugger was not safer than alternatives available on the market.

105. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Bair Hugger.

106. The concealment of information by the Defendants about the risks of the Bair Hugger was intentional, and the representations made by Defendants were known by the Defendants to be false.

107. The concealment of information and the misrepresentations about Bair Hugger were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's doctors, rely upon them.

108. Plaintiff and Plaintiff's physicians relied upon the representations and were unaware of the substantial risks of the Bair Hugger which the Defendants concealed from the public, including Plaintiff and Plaintiff's physicians.

109. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant. In addition, plaintiff must take antibiotics for the rest of her life. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

110. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and/or severally, as follows:

1. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00);
2. If allowed by the Court upon motion, an award of punitive damages in the amount to be proven at the time of trial, and sufficient to punish the Defendants or to deter the Defendants and others from repeating the injurious conduct alleged herein;
3. For pre-judgment and post-judgment interest on the above general and special damages;
4. For costs of this suit and attorneys' fees; and
5. For all other relief that Plaintiff may be entitled to at equity or at law.
6. For such further and other relief that this Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

Respectfully Submitted,

DATED this 19th day of August, 2015.

MESHBESHER & SPENCE, LTD

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